

REMARKS

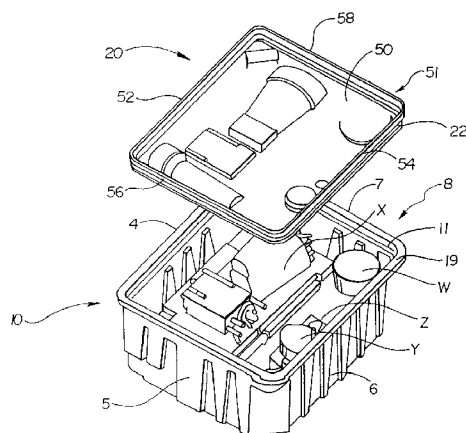
Claims 31, 32, 34-50 and 99-102 remain pending in the present Application. Claims 31, 49, and 99 having been amended. New The claims set forth above include markings to show the changes made by way of the present amendment, deletions being in ~~strikeout~~ or [[double brackets]] and additions being underlined.

In response to the Office Action mailed October 15, 2009, Applicant respectfully requests the Examiner to reconsider the above-captioned application in view of the foregoing amendments and the following comments.

The Proposed Combination of Johnson/Smith Does Not Make Amended Claim s 31, 35-48, and
124 Obvious

Claims 31, 35-48, and 124 stand rejected under 35 U.S.C. § 103(a) as being obvious under Johnson *et al.* (U.S. Patent No. 6,311,838) (“Johnson”) in view of Smith *et al.* (U.S. Patent No. 6,402,724) (“Smith”). Applicant respectfully traverses the present rejection. However, to expedite the prosecution of the present application, Applicant has amended Claim 31. Applicant submits that no new matter has been added and that the amendments are supported in the specification. *See, e.g.*, paragraph [0224]. Applicant also expressly reserves the right to further prosecute the original versions of Claim 31 and any claims dependent on it through continuation practice.

Johnson discloses an integrated packaging system for packaging medical components. See Figure 1 from Johnson, reproduced below.



On page 3 of the Office Action, the Examiner asserts that Johnson teaches the claimed kit except for the flexible sheet and that Smith teaches “a wound irrigation shield that includes a flexible sheet with an adjustable aperture as set forth in the abstract.”

Applicant submits that Johnson does not teach a flexible sheet as indicated in the Office Action. Johnson also does not teach a basin for collecting irrigation fluid used during an irrigation procedure. Persons skilled in the art would not consider the packaging container 10 as a basin for collecting irrigation fluid during an irrigation procedure.

Smith teaches a splash shield for use in wound irrigation. The splash shield is made of flexible material “to adapt to the fluid end portion of any number and variety of irrigation fluid delivery devices.” Smith, Abstract. See also Figures 1 and 2 from Smith reproduced below.

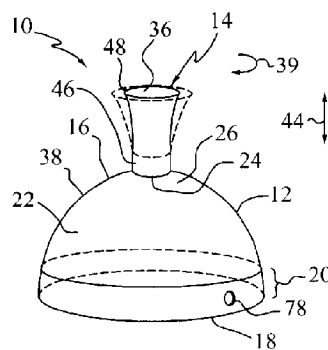


FIG. 1

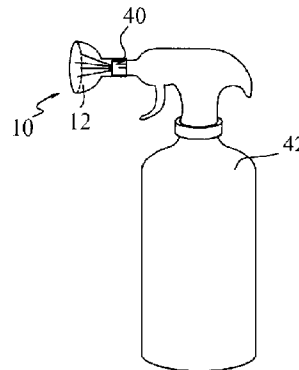


FIG. 2

In contrast, Claim 31 recites, among other recitations, “a transparent flexible sheet having an aperture configured to engage an irrigation device; a basin for collecting irrigation fluid used during an irrigation procedure, the basin being sterilized and made of a biocompatible hypoallergenic material; wherein the aperture, in an enlarged state, is configured to fit over a conical splash shield extending distally from a collar attached to a tip of the irrigation device; wherein the flexible sheet is sized to cover a wound area and the basin.”

Applicants recognize that Smith teaches a *conical* version of a “**splash shield**”, which is recited in Claim 31. However, Applicant notes that the outstanding rejection cannot rely on the conical splash shield of Smith as teaching the recited combination of a **transparent flexible sheet with an aperture configured to fit over a conical splash shield**. Rather, the conical splash shield of Smith can only be used to teach the recited conical splash shield, not the above-noted

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combination of *two things*. Further, Applicant submits that persons skilled in the art would recognize that it would be impossible to place one of the Smith splash shields over another such splash shield.

This distinction between the flexible sheet and a conical splash shield is important, especially in the area of orthopedic surgery, in which large amounts of irrigation fluid is used. For example, bone fragments, and other contaminants pose a risk to the practitioner in that they can be splashed on to the practitioner during a wound irrigation procedure. *See, e.g.*, paragraphs [0009]-[0011]. Prior art conical splash shields that are fit onto the end of an irrigation device do not provide adequate protection for the practitioner. *See, e.g.*, Figure 2 of Robinson shown above. The flexible sheet as described in certain embodiments of the present application provides more surface area for protection.

As noted above, Claim 31 now recites, “a **transparent** flexible sheet” having an aperture configured to fit over an irrigation device.

In contrast, no obvious combination of Smith and Johnson would result in any of the variations of the transparent flexible sheet now recited in Claim 31.

Applicant thus submits that the combination of Johnson and Smith does not render Claims 31 obvious. Therefore, Applicant requests that the Examiner withdraw the rejection of Claim 31 and pass Claim 31 to allowance. Additionally, Applicant submits that Claims 35-48, and 124 also define over the cited references, not only because they depend from Claim 31, but also on their own merit.

The Proposed Combination of Holloway/Smith Does Not Make Amended Claim 49 Obvious

Independent Claim 49 stands rejected under 35 U.S.C. § 103(a) as being obvious under Holloway *et al.* (U.S. Patent No. 5,381,562) (“Holloway”) in view of Smith. Applicant respectfully traverses the present rejection. However, to expedite the prosecution of the present Application, Applicant has amended Claim 49. Applicant submits that no new matter has been added and that the amendments are supported in the specification. *See, e.g.*, paragraph [0224]. Applicant reserves the right to further prosecute the original version of Claim 49 through continuation practice.

Holloway discloses a contoured basin. Smith is discussed above. On page 6 of the Office Action, the Examiner indicates that Smith teaches “a wound irrigation shield that includes a

flexible sheet with an adjustable aperture as set forth in the abstract.” Applicant wishes to point out that **neither the Abstract nor any other portion of the Smith reference teaches, suggests, or even includes the word “sheet.”** In fact, a full text search of the Smith reference reveals that the term “sheet” does not appear at all in the Smith reference.

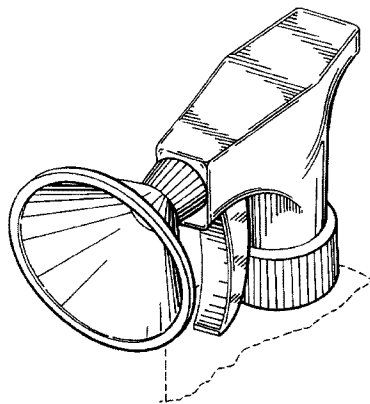
Thus, for at least the same reasons discussed above with respect to Claim 31, Smith does not teach either a flexible sheet being configured to fit over a conical splash shield or a flexible sheet sized to cover a wound area and a basin. Holloway, which teaches a basin, does not rectify these failures.

For at least the forgoing reasons, Applicant submits that the combination of Holloway and Smith does not render Claim 49 obvious. Therefore, Applicant requests that the Examiner withdraw the rejection of Claim 49 and pass Claim 49 to allowance.

The Proposed Combination of Marogil/Smith Does Not Make Amended Claim 99 Obvious

Claim 99 stands rejected under 35 U.S.C. § 103(a) as being obvious under Marogil (Des 386,684) (“Marogil”) in view of Smith. Applicant respectfully traverses the present rejection. However, to expedite the prosecution of the present application, Applicant has amended Claim 99. Applicant submits that no new matter has been added and that the amendments are supported in the specification. *See, e.g.*, paragraph [0224]. Applicant also expressly reserves the right to further prosecute the original versions of Claim 99 and any claims dependent on it through continuation practice.

Marogil teaches an ornamental design for an antiseptic spray nozzle and guard. See Figure 1 of Margil reproduced below. Smith is discussed above.



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On page 8 of the Office Action, the Examiner notes that “it would have been obvious... to provide the splash shield of Marogil with the flexible sheet taught by Smith.” As mentioned above with respect to Claim 31, the Smith shield is not a *sheet*. Rather, the Smith shield is a *conical* splash shield that appears to be nearly identical in shape as the conical splash shield of Marogil. Thus, Applicant submits that one of ordinary skill in the art would not one conical splash shield over another conical splash shield.

For at least the same reasons discussed above for Claim 31, Smith does not teach either a transparent flexible sheet being configured to fit over a conical splash shield or a flexible sheet sized to cover a wound area and a basin. Marogil, which teaches a spray nozzle and guard, does not rectify these failures.

For at least the forgoing reasons, Applicant submits that the combination of Marogil and Smith does not render Claim 99 obvious. Therefore, Applicant requests that the Examiner withdraw the rejection of Claim 99 and pass Claim 99 to allowance.

Dependent Claims 32, 34-48, 50, 100-102, 124, and 125 Depend from Independent Claims 31, 49, or 99.

Applicant submits that Claims 32, 34-48, 50, 100-102, 124, and 125 and also define over the cited references, not only because they depend from one of Claims 31, 49, or 99, but also on their own merit.

No Disclaimers or Disavowals

Although the present communication may include alterations to the Application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this Application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicant has made any disclaimers or disavowals of any subject matter supported by the present Application.

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SUMMARY

The undersigned has made a good faith effort to respond to all of the rejections and objections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicant's attorney in order to resolve such issue promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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